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## NOV 2 4 2000

David T. Read Acting Director Regulatory Policy Staff, CDER Food and Drug Administration 1451 Rockville Pike, HFD-7 Rockville, MD 20852

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,598,089. The application was filed on May 21, 1999, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Telephone inquiries regarding this matter should be directed to the undersigned at (703)306-3159.

Karin Tyson Senior Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner for Patent Examination Policy

cc: George W. Johnston HLR Technology Corporation Patent Law Department 340 Kingsland Street Nutley NJ 07110